REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of three months of the period for response to the Office Action. Our cheque in respect of the prescribed fee is enclosed.

The Examiner withdrew claims 3 and 4 from consideration as encompassing non-elected nucleotide species. These claims have been deleted without prejudice to applicants right to file a divisional or continuation application directed thereon. Claim 5 has been corresponding amended.

The Examiner maintained objection to the informal drawings. As clearly stated in the quotation made in the Office Action:

> "Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability".

The applicants are availing themselves of this opportunity, as previously stated.

The Examiner maintained rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite.

The Examiner comments have been reviewed. The Examiner considered that certain strains not producing the 200 kDa protein were not excluded. However, the language of claim 2 clearly excludes these strains. As stated in claim 2:

> "...said another strain of *Moraxella catarrhalis* in (c) is a strain as identified in Table 1A other than strains 4223, Q8 and LES-1 and expressing an about 200 kDa protein."

Thus, the strains in claim 2 are those of Table 1A identified as expressing a 200 kDa protein (other than strains 4223, Q8 and LES-1), thereby clearly excluding those which do not produce such protein. The language of claim 2 has been modified in an attempt to meet the Examiner's comments.

Having regard thereto, it is submitted that claim 2 can no longer be considered indefinite and the rejection thereof under 35 U.S.C. 112, second paragraph, should be withdrawn.

The Examiner maintained rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite.

The preparation of a C-terminal fragments of the 200 kDa protein is clearly described in Example 15. A person skilled in the art provided with this description, would clearly understand the meaning of the terminology made in claim 9.

Having regard thereto, it is submitted that claim 9 is clear in scope and the rejection thereof under 35 U.S.C. 112, second paragraph, should be withdrawn.

The Examiner maintained rejection of claims 7 and 8 under 35 U.S.C. 112, first paragraph, as being non-enabled.

It is already stated, under the signature of the undersigned that all restrictions to public access to the deposits will be irrevocably removed upon the grant of a patent on this application.

Having regard to this statement, it is submitted that this rejection is overcome. The Examiner states in the Office Action that the statement would be sufficient to overcome the rejection. Accordingly, the rejection of claims 7 and 8 under 35 U.S.C. 112, first paragraph, should be withdrawn.

The Examiner maintained rejection of claims 1, 2, 5, 6, 9 and 10 under 25 U.S.C. 102(e) as being anticipated by Sasaki et al., U.S. Patent No. 5,808,024.

The Examiner states that claim 1 "encompasses every strain of *Moraxella catarrhalis*". This is clearly not the case. Claim 1 includes only strain 4223, Q8 and LES-1 (parts (a) and (b)) and those having a nucleotide sequence having the specific characteristics of part (c):

> "...a tract of consecutive G nucleotides which is 3 or a multiple thereof in length, an ATG start codon about 80 to 90 bp upstream of said tract and said tract being located

between amino acids 25 and 35 encoded by the nucleotide sequence."

Thus, excluded from claim 1 are strains of *Moraxella catarrhalis* which do not have these characteristics.

The Examiner critizies the term "having". This term, it is submitted, is limited in scope to the specific items recited, which are recited as "consisting of". If it helps the Examiner's understanding of the meaning of the claims, claim 1 has been amended to use the term "consisting of" rather than "having".

In addition, it is clear that claim 1 (a) is intended to refer to a sequence fully complimentary to the nucleic acid sequences, otherwise a partial sequence would have been referred to. Again, to assist the Examiner's understanding of the claim, part 1(a) has been amended to refer to sequence fully complementary to the nucleic acid sequences. However, sequence identity, to which the Examiner refers, is different from a sequence which is complementary to a nucleic acid sequence.

The Sasaki et al. reference does not describe any nucleotide sequence which is the same as SEQ ID Nos. 5, 6, 8 or 10, as stated in part 1(a) or the fully complimentary sequences thereto. In addition, the derieved amino acid sequence from these strains (SEQ ID Nos: 7, 9 and 11) are not described in Sasaki et al.

With respect to part (c) of claim 1, the Examiner is incorrect to state that:

> "...the prior art reference does not have to expressly identify any start codon or open reading frame in a nucleotide sequence".

Part (c) specifically requires that the nucleotide sequence encodes an about 200 kDa outer membrane protein of another strain of *Moraxella catarrhalis* which is characterized by:

- a tract of consecutive G nucleotides which is 3 or a multiple thereof in length,

- an ATG start codon about 80 to 90 bp upstream of said tract,
- said tract being located between about amino acids 25 to 35 encoded by the nucleotide sequence.

In order, therefore, to determine whether or not a reference anticipates this part of claim 1, it is essential that an ATG start codon be identified as well as a open reading frame.

While the Examiner is correct that the brief description of Figure 6 of the Sasaki et al. reference states that the nucleotide sequence of the gene has an open reading frame of the about 200 kDa outer membrane protein of *Moraxella catarrhalis*, no such open reading frame is identified in the Figure.

With respect to the Examiner's interpretation of the description "about 80 to 90 bp", the Examiner identifies as ATG codon 102 bp upstream from a tract of these consecutive GGG nucleotides. The Examiner refers to "attached" Figure 6 with the ATG and GGG nucleotides boxed and highlighted in yellow There was no such attachment to the Office Action.

If the Examiner is referring to the attachment to applicant's amendment of March 25, 2002, it must be stated:

- the ATG codon identified is not identified by Sasaki as a start codon and not all ATG codons are start codons
- the G tract contains IOGs, which is not a multiple of 3, as referred by applicant's claims
- Sasaki et al subsequently identified the start codon as the GTG, (newly-cited WO 96/34960), also boxed and highlighted in applicants enclosure to the March 25, 2002 Amendment, which is downstream of the IOG tract in Sasaki et al.

Accordingly, it is submitted that Sasaki et al. does not anticipate claim 1 nor any of the claims dependent thereon and hence the rejection of claims 1, 2, 5, 6, 9 and 10 under 35 U.S.C. 102(a) as being anticipated by Sasaki et al. should be withdrawn.

The Examiner personally rejected claims 1, 2, 5, 6, 9 and 10 under the judicially created docterine of obviousness-type double patenting over claims 14 to 23 of copending application 08/945,567.

It is noted that the rejection is provisional since the claims of 08/945,567 have not yet been patented. No action, therefore, is required at the present time with respect to this rejection.

The Examiner rejected claims 1, 2 and 5 to 10 under 35 U.S.C. 112, first paragraph, on the basis that, while the specification is enabled for an isolated and purified nucleic acid molecule having a nucleotide sequence as recited in part (c) which encodes a 200 kDa outer membrane protein from certain strains of *Morexalla catarrhalis*, for example, strains 4223, LES-1 and Q8, does not reasonably provide enablement for such a molecule from every strain of *Moraxella catarrhalis* encompassed in Table 1A other than 4223, Q8 and LES-1.

The rejection is difficult to answer, since the Examiner does not identify the "certain strains" in respect of which the Examiner considers the claims to be enabled. The inclusion in the rejection of claims 7 and 9, directed to specific plasmids, which are clearly enabled, in particularly puzzling.

Parts (a) and (b) of claim 1 specifically defines SEQ ID Nos. for the sequence doe strains 4223, Q8 and LES-1.

Part (c) defines a nucleotide sequence which:

- encodes an about 200 kDa outer membrane protein of another strain (i.e. other than 4223, Q8 and LES-1) which is characterized by:
  - a tract of consecutive G nucleotides which is 3 or a multiple thereof in length

- an ATG start codon about 80 to 90 bp upstream of the tract
- the tract being located between amino acid 25 and 25 encoded by the nucleotide sequenc

Applicant has shown in Table 1A strains which meet these criteria, being strains which strongly express the 200 kDa protein. Table 5, to which the Examiner refers, is the result of analysis of the 5' end of the 200 kDa gene from 24 strains of *Moraxella catarrhalis*, which clearly suggests that the number of G nucleotides in the G tract are as a regulator of expression.

Having regard thereto, it is submitted that claims 1, 2 and 5 to 10 are fully enabled by the specification and hence the rejection thereof under 35 U.S.C. 112, first paragraph, should be withdrawn.

The Examiner rejects claims 1, 2 and 5 to 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, with respect to the term "another strain".

With respect thereto, it is submitted there is no indefiniteness. Parts (a) and (b) of claim 1 specifically refer to strains 4223, Q8 and LES-1, so that that the term "another strain" clearly refers to another strain of *Moraxella catarrhalis* other than strains 4223, Q8 and LES-1.

Having regard thereto, it is submitted there is no indefiniteness and hence the rejection of claims 1, 2 and 5 to 10 under 35 U.S.C. 112, second paragraph, should be withdrawn.

The Examiner rejects claims 1, 5 to 7, 9 and 10 under 35 U.S.C. (c) as being anticipated by Loosmore et al., on the basis of the disclosure in Loosmore et al. of plasmid pKS348.

The inventors of this application, namely Sheena M. Loosmore, Ken Sasaki, Yan-Ping Yang and Michel H. Klein are the same inventors as identified in Loosmore t al., namely Sheena M. Loosmore, Yan-Ping Yang, Michel H. Klein and Ken Sasaki, albeit in a different

order. Citation under 35 U.S.C. 102(e) requires that there be a different inventive entity.

RECITATION

In addition, this application and Loosmore et al. have a common assignee, Aventis Pasteur Limited (formerly Connaught Laboratories Limited). Under the circumstances, it is submitted that a rejection under 35 U.S.C. 102(e) cannot be maintained.

Accordingly, it is submitted that claims 1, 5 to 7, 9 and 19 are not anticipated by Loosmore et al. and hence the rejection thereof under 35 U.S.C. 102(e) as being anticipated by Loosmore et al. should be withdrawn.

The Examiner rejected claims 1, 5, 6, 9 and 10 under 35 U.S.C. 102(b) as being anticipated by Sasaki et al., WO 96/34960 ('960).

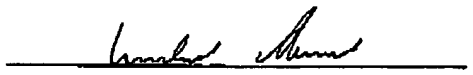
The Sasaki reference and its contents are fully discussed in the specification. The comments made above with respect to Sasaki U.S. Patent No. 5,808,024 apply equally there. The Examiner refers to an attached sequence search report. No such sequence search report is attached to the Office Action. In any event, the Examiner is referring to sequence identity, which is unrelated to the complement of a related response. As has previously discussed, Sasaki '960, in common with Sasaki's U.S. Patent No. 5,808,024, does not disclose the nine G sequence present in SEQ ID No. 6, but rather IOG sequence.

There is no anticipation, therefore, of claims 1, 5, 6, 9 and 10 by Sasaki '960 and hence the rejection should be withdrawn.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,



M.I. Stewart
Reg. No. 24,973

Toronto, Ontario, Canada,
(416) 595-1155
FAX No. (416) 595-1163

Appl. No. 09/361,619

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 3 and 4 have been cancelled.

Claims 1, 2 and 5 have been amended as follows:

1. (Twice Amended) An isolated and purified nucleic acid molecule consisting of [having] a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence consisting of SEQ ID Nos: 5, 6, 8 or 10 or the fully complementary sequence thereto,

(b) a nucleotide sequence encoding an about 200 kDa outer membrane protein of strain of *Moraxella catarrhalis* and consisting of SEQ ID Nos: 7, 9 or 11, and

(c) a nucleotide sequence encoding an about 200 kDa outer membrane protein of another strain of *Moraxella catarrhalis* which is characterized by a tract of consecutive G nucleotides which is 3 or a multiple thereof in length, an ATG start codon about 80 to 90 bp upstream of said tract and said tract being located between amino acids 25 and 35 encoded by the nucleotide sequence.

2. (Amended) The nucleic acid molecule of claim 1 wherein said another strain of *Moraxella catarrhalis* in (c) is a strain expressing an about 200 kDa protein as identified in Table 1A other than strains 4223, Q8 and LES-1 [and expressing an about 200 kDa protein].

5. (Amended) A vector for transforming a host comprising a nucleic acid molecule as claimed in claims [any one of claims] 1 or 2 [1 to 4].